K043502

JAN 14 2005

Section 6

510(k) Summary

6 Fr Poly Per-Q-Cath®3 Triple Lumen PICC

510(k) Summary of Safety and Effectiveness Information
21CFR 807.92

6.1 Submitter Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Subsidiary of C.R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 7136
Fax Number:	(801) 595-5425
Contact Person:	[illegible]
Date of Preparation:	16 December, 2004

6.2 Device Name

Device Name:	Poly Per-Q-Cath®3 Triple Lumen PICC Catheter
Trade Name:	Poly Per-Q-Cath®3 Triple Lumen PICC Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Panel:	General Hospital
Classification Name:	80LJS – Long Term Intravascular Catheter 21 CFR 880.5970, Class II Peripherally Inserted Central Catheter (PICC)

6.3 Predicate Device Name

Device Name:	Poly Per-Q-Cath® PICC Catheter
Trade Name:	Poly Per-Q-Cath® PICC Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Long Term Intravascular Catheter (80 LJS)
Premarket Notification:	K034019, concurrence date – January 21, 2004

6.4 Device Description

Principle of Operation

There are no new operating principles. The modified 6 Fr Poly Per-Q-Cath®3 TL PICC catheter relies on the same basic, fundamental scientific technology as the predicate 6 Fr DL Poly Per-Q-Cath PICC. The devices serve as conduit for fluids and blood into, and out of, the central venous system.

6.5 Intended Use

The Triple Lumen PICC is intended for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling.

The intended use has not changed.

6.6 Indications for Use

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The indications for use have not changed from the predicate Poly Per-Q-Cath PICC (K034019).

The Poly Per-Q-Cath® Triple Lumen PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling. For blood therapy, it is recommended that a 4 French or larger catheter be used.

6.7 **Summary of Technological Characteristics in Relation to the Predicate Device**

Does the new device have the same technological characteristics, e.g. design, material, etc.?

Not in all regards. The 6 Fr Poly Per-Q-Cath® TL PICC has some minor differences from the predicate 6 Fr DL Poly Per-Q-Cath PICC. However, the basic fundamental scientific technology of the catheter has not changed.

Could the new characteristics affect safety or effectiveness?

Yes. The new characteristics could affect safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?

No. There are no new types of issues of safety and effectiveness.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The following FDA guidance documents and international standards were used to evaluate the device's performance:

- *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, March 16, 1995*
- *ISO 10555-1:1997, Sterile, Single-Use Intravascular Catheters, General requirements*
- *ISO 10555-1:1997, Sterile, Single-Use Intravascular Catheters, General requirements, Amendment 1*
- *ISO 10555-3:1997, Sterile, Single-Use Intravascular Catheters, Central venous catheters*
- *AAMI/ANSI/ISO 11135:1994, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*

Design validation was performed to meet the recommendations of the FDA guidance document, *Design Control Guidance for Medical Device Manufacturers*, dated March 11, 1997.

Biocompatibility requirements of ISO 10993 *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing* and the FDA Modified ISO 10993 Test Profile for externally communicating, blood contacting, long-term devices were met. All materials used in the manufacture of the subject device were previously cleared for similar applications by Bard Access Systems.

Are performance data available to assess effects of new characteristics?

Yes. Verification and validation testing was performed according to protocols based on the above referenced guidance document recommendations and standards, as well as in accordance with in-house protocols.

Do performance data demonstrate equivalence?

Yes. Performance data gathered in design verification and validation testing demonstrated that the 6 Fr Poly Per-Q-Cath® TL PICC is substantially equivalent to the predicate 6 Fr DL Poly Per-Q-

Cath PICC, and the risks associated with use of the new device were found acceptable when evaluated by FMEA.

6.8 Conclusion

The 6 Fr Poly Per-Q-Cath® TL PICC meets all the predetermined performance acceptance criteria of the testing performed and, based on FDA's decision tree, is substantially equivalent to the predicate device 6 Fr DL Poly Per-Q-Cath PICC, K034019, cleared January 21, 2004.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2005

Ms. Lynn M. Kirchoff
Regulatory Affairs Specialist
Bard Access Systems, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K043502
Trade/Device Name: 6 Fr Poly Per-Q-Cath®3 Triple Lumen PICC
Regulation Number: 880.5970
Regulation Name: Percutaneous, Implanted Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: December 17, 2004
Received: December 20, 2004

Dear Ms. Kirchoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

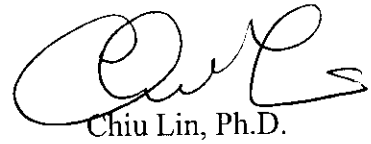
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043502

Indications for Use

510(k) Number (if known): K043502

Device Name: **6 Fr Poly Per-Q-Cath®3 Triple Lumen PICC**

Indications for Use:

The Poly Per-Q-Cath®3 Triple Lumen PICC is indicated for short or long term peripheral access to the centra venous system for intravenous therapy and blood sampling. For blood therapy, it is recommended that a 4 Frenc or larger catheter be used.

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K043502